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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/974,913 | 10/12/2001 | Thomas T. Hubscher | Dexall-1 | 9959 |

7590 06/23/2003
Jonathan E. Grant
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2120 L Street, N.W.
Washington, DC 20037

EXAMINER

NGUYEN, BAO THUY L.

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1641

DATE MAILED: 06/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/974,913

Applicant(s)

THOMAS HUBSCHER

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment filed 10/12/01 has been received. Claims 1-26 and 41-66 have been canceled. Claims 27-40 are pending.

Drawings

2. This application, filed under former 37 CFR 1.60, lacks formal drawings. The informal drawings filed in this application are acceptable for examination purposes.

3. New corrected drawings are required in this application. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. Claims 27-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is vague and indefinite with respect to the recitation of a labeling site comprising colorimetric labeled analytes. It is unclear if the device is intended for the detection analytes such as antibodies in a sample or for the detection of analytes such as antigens, etc. In general, the term "analyte" is defined as "any substance or chemical constituent of blood, urine, or other body fluid that is analyzed, therefore, the recitation of a labeling site comprising

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"labeled analyte" is confusing. Furthermore, what is the relationship between the antibodies in the sample and the labeled analyte? Will they bind to each other?

Claim 27 is also confusing with respect to the recitation of the reaction site binding to the colorimetric immune antibody complexes because it is unclear what is in the reaction site that allows for this binding to occur. The claim recite a reaction for detecting IgG antibodies, for example, without specifically stating what is present in the reaction site.

The recitation of "said colorimetric immune-antibody complexes" lack antecedent support. The recitation of a colored line appearing at each of the reaction site where the antibodies in the sample bind to the colorimetric labeled analyte is confusing because it appears that the labeled analyte is present at the reaction site.

Line 8, "said" should be removed for clarity.

Claims 30 and 31 are confusing because it is unclear if the device is designed to detect analytes such as antibodies from *H. pylori* for example, or if the "labeled analyte" is a reagent designed to capture antibodies in a sample. Clarification is required.

Claim 32, "the colored solid phase" lacks antecedent support.

Claim 33 is confusing with respect to the recitation of "specific antibodies" because it is unclear which specific antibodies is being claimed, those in the sample?

Claim 36 is vague and indefinite because it is unclear which substances reaction with IgG is being claimed and where they are disposed on the device of claim 27.

Claim 37 is confusing for the same reason stated in claim 36 and further, because the recitation of "said antibody" lack antecedent support.

Claim 39 is vague and indefinite because it is unclear which IgG reacting substance is disposed as the sample site and for what purpose. Is it a capture substance?

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 27-40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brizgys et al (US 5,807,752).

Brizgys discloses a device comprising a porous carrier having a requisite number of receptors for analytes to be determined. See column 3, lines 20-28 and figure 1. The device also comprising a labeled binding partner for the analyte to be determined combine with a blocking agent. The label may be a gold sol, colored latex particle, etc. See column 3, lines 29-48. The test carrier also has wicking means at one end, and a waste means at the other. Capture receptors are impregnated on the device at specific locations. Brizgys teaches that both the capture and labeled receptors may be antibodies, antigens, protein A including polyclonal and monoclonal antibodies. See column 4, lines 14-16; lines 34-40 and column 5, lines 18. In one specific embodiment, a device comprising for analyte specific antibodies and one control was made to detect IgA, IgD, IgE, IgM and IgG. See columns 5 and 6.

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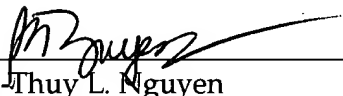
Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bao-Thuy L. Nguyen
Primary Examiner
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June 17, 2003